RESULTS OF A COCHRANE REVIEW

ORAL GALACTOGOGUES (NATURAL THERAPIES OR DRUGS) FOR INCREASING BREAST-MILK PRODUCTION IN MOTHERS OF NON-HOSPITALIZED TERM INFANTS

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Study types included: Randomized Controlled Trials (RCTs) and Quasi-RCTs

Participants Mothers breastfeeding or expressing for term healthy infants <6 mos of age

Intervention Comparisons:

1. Pharmacological oral galactagogue vs Placebo or no treatment
2. Natural oral galactogogue vs Placebo or no treatment
3. Galactagogue vs another Galactagogue

Primary Outcome measures

- Proportion of infants breastfeeding (excl or any) at 3, 4 and 6 mos postpartum
- Infant weight in trials where infants are receiving only own mothers' milk
- Volume of human milk measured in a specified amount of time

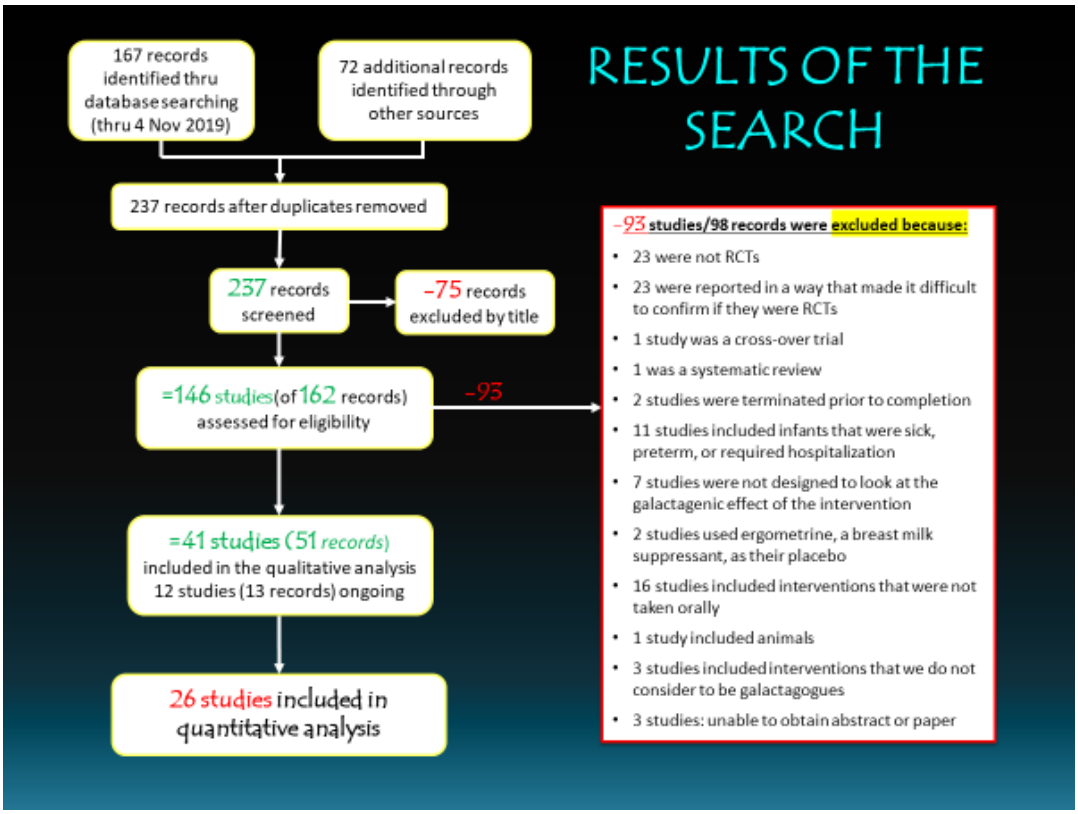
Secondary Outcome measures

- Adverse effects in mother or baby
- Ability of parent to reduce or stop formula supplementation
- Parental psychological status: satisfaction scores, depression scale, etc.

SEARCH STRATEGY: Standard search of Cochrane data base for Pregnancy and Childbirth group, derived from: Trial Registers, Medline, Embase, CINAHL, searches of 30 journals and proceedings of major conferences, weekly awareness alerts for 44 journals plus BioMed Central alerts., regional & content-specific databases; regional and content specific data bases; Also HERDIN (Philippines) and Napralert with special search terms. Secondary sources included following references, personal article collection of author LM. No language, geographic or date restrictions.

Excluded studies:

- **Pharmacological:** arginine aspartate (1); domperidone (6); growth hormone (3); iodine (3); luteotropin (1); metoclopramide (7); metoclopramide, domperidone and ferolactan (1); obron multivitamin (1); orgametril (1); oxytocin (9); oxytocin & sulpiride (1); Oestrogen and progestogen (1); Pitocin (1); pseudophedrine (1); sulpiride (1); thyrotropin releasing hormone (1).
- **Botanical:** Chasteberry (3); collagen soup (1); fenugreek (3); fenugreek/garlic mix (1); goat's rue (2); goat's rue/silymarin (1); garlic (1); glutamic acid (1); hedge nettle (3); humana still-tea (1); kyuki-choketu (2); Lactare (6); Leptaden (8); moringa (1); nutrition supplement (1); milk and eggs (1); Motherlove More Milk Plus (1); Mu-ying-li (1); Oligoplex/vitex (2); pectin extract (1); molocco placental extract (1); sesame (1); shatavari (1); Torbangun (2); various Japanese medicines (1); Yangxueshengru oral liquor (1)



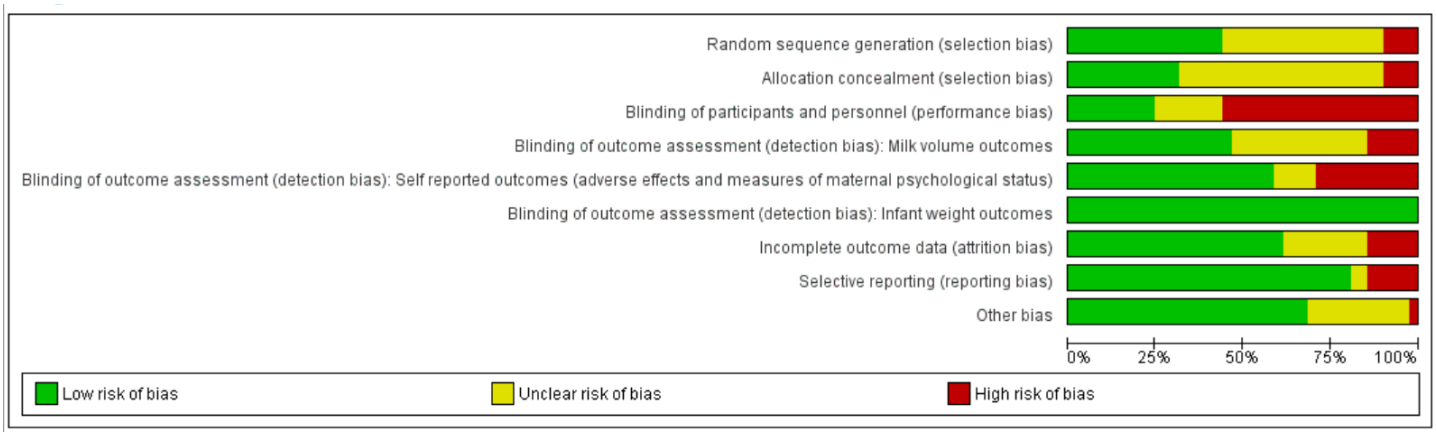
Characteristics of included studies

- **Locations:** North America (1); Latin America (3); Europe (3); Eurasia (6); East Asia (8); West Asia/Africa (4); South Asia (6); Southeast Asia (13)
- **Participants:** C-section only (2); Late term pregnancy only (1); Primips only (5); Female babies only (1); Infants 0-14d (21); Lactation deficient (18); older infants 2wks-6 mos (16); working mothers separated 8 hrs (1); (No milk problems (?);
- **Pharmacological interventions (4):** domperidone (2); metoclopramide (3); sulpiride (3); TRH (2);
- **Natural interventions (29):** Shatavari capsules (1); Cui Ru soup (1); Fennel tea (1); Fenugreek tea (1); Lactogenic food menu (1); Ginger capsules (1); Cottonseed capsules (1); Humana Still-Tee (2); Ixbut infusion (1); Malunggay/moringa capsules (4); Shatavari combo capsules (1); Pork leg soup (1); Shirafza drops (10: Silymarin sachet (1)
- **Galactagogue vs Galactagogue:** Domperidone vs malunggay (1); Torbangun vs fenugreek vs molocco (1); Mu Er Wu You vs Kun Yuna tong ru fu ye soup (1); Ru quan chong ji vs shengruzhi soup; fenugreek vs palm dates (1); fennel vs fenugreek black teas (1); Chanbao vs bu xue shen ru vs no intervention (1)

Studies by outcome:

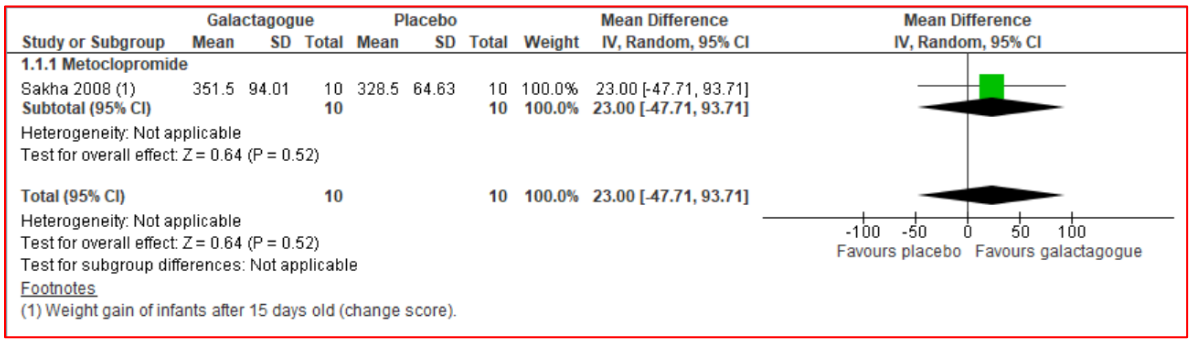
- Duration of breastfeeding: (3)
- Volume of milk measured (28)
    - By pre- and -post feeds (7)
    - By pre- and post feeds + residual milk (2)
    - Expression of milk by hand or pump (11)
    - Changes in breast dimensions (1)
    - Lai 4-hr pumping method (1)

- Infant weight (9) measured in various ways (total gain, weekly gain, mean % gain, etc)
- Adverse effects (17, but only 3 pre-specified)
- Ability to reduce supplementation (6)
- Maternal psychological status (4)



Risk of bias graph: review of authors' judgements about each risk of bias item presented as percentages across all included studies

Comparison 1.1 Infant Gain



Study or Subgroup	Galactagogue Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
1.1.1 Metoclopromide								
Sakha 2008 (1)	351.5	94.01	10	328.5	64.63	10	100.0%	23.00 [-47.71, 93.71]
Subtotal (95% CI)			**10**			**10**	**100.0%**	**23.00 [-47.71, 93.71]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.64 (P = 0.52)								
Total (95% CI)			**10**			**10**	**100.0%**	**23.00 [-47.71, 93.71]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.64 (P = 0.52)								
Test for subgroup differences: Not applicable								

Mean Difference IV, Random, 95% CI

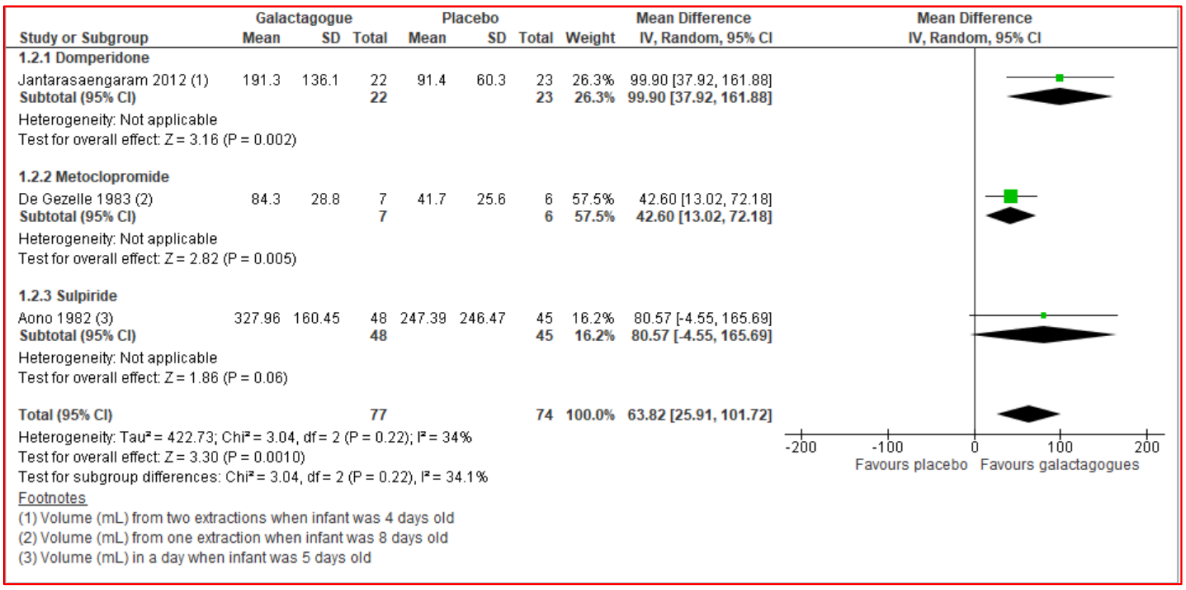
-100 -50 0 50 100

Favours placebo Favours galactagogue

Footnotes

(1) Weight gain of infants after 15 days old (change score).

Comparison 1.2: Milk Volume



Study or Subgroup	Galactagogue Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
1.2.1 Domperidone								
Jantarasaengaram 2012 (1)	191.3	136.1	22	91.4	60.3	23	26.3%	99.90 [37.92, 161.88]
Subtotal (95% CI)			**22**			**23**	**26.3%**	**99.90 [37.92, 161.88]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 3.16 (P = 0.002)								
1.2.2 Metoclopromide								
De Gezelle 1983 (2)	84.3	28.8	7	41.7	25.6	6	57.5%	42.60 [13.02, 72.18]
Subtotal (95% CI)			**7**			**6**	**57.5%**	**42.60 [13.02, 72.18]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 2.82 (P = 0.005)								
1.2.3 Sulpiride								
Aono 1982 (3)	327.96	160.45	48	247.39	246.47	45	16.2%	80.57 [-4.55, 165.69]
Subtotal (95% CI)			**48**			**45**	**16.2%**	**80.57 [-4.55, 165.69]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.86 (P = 0.06)								
Total (95% CI)			**77**			**74**	**100.0%**	**63.82 [25.91, 101.72]**
Heterogeneity: Tau² = 422.73; Chi² = 3.04, df = 2 (P = 0.22); I² = 34%								
Test for overall effect: Z = 3.30 (P = 0.0010)								
Test for subgroup differences: Chi² = 3.04, df = 2 (P = 0.22), I² = 34.1%								

Mean Difference IV, Random, 95% CI

-200 -100 0 100 200

Favours placebo Favours galactagogues

Footnotes

(1) Volume (mL) from two extractions when infant was 4 days old

(2) Volume (mL) from one extraction when infant was 8 days old

(3) Volume (mL) in a day when infant was 5 days old

Summary of Comparison 1

Pharmacological oral galactagogues compared to placebo or no treatment for increasing breast milk production in mothers of non-hospitalised term infants

Patient or population: increasing breast milk production in mothers of non-hospitalised term infants
Setting: Community
Intervention: pharmacological oral galactagogues
Comparison: placebo or no treatment

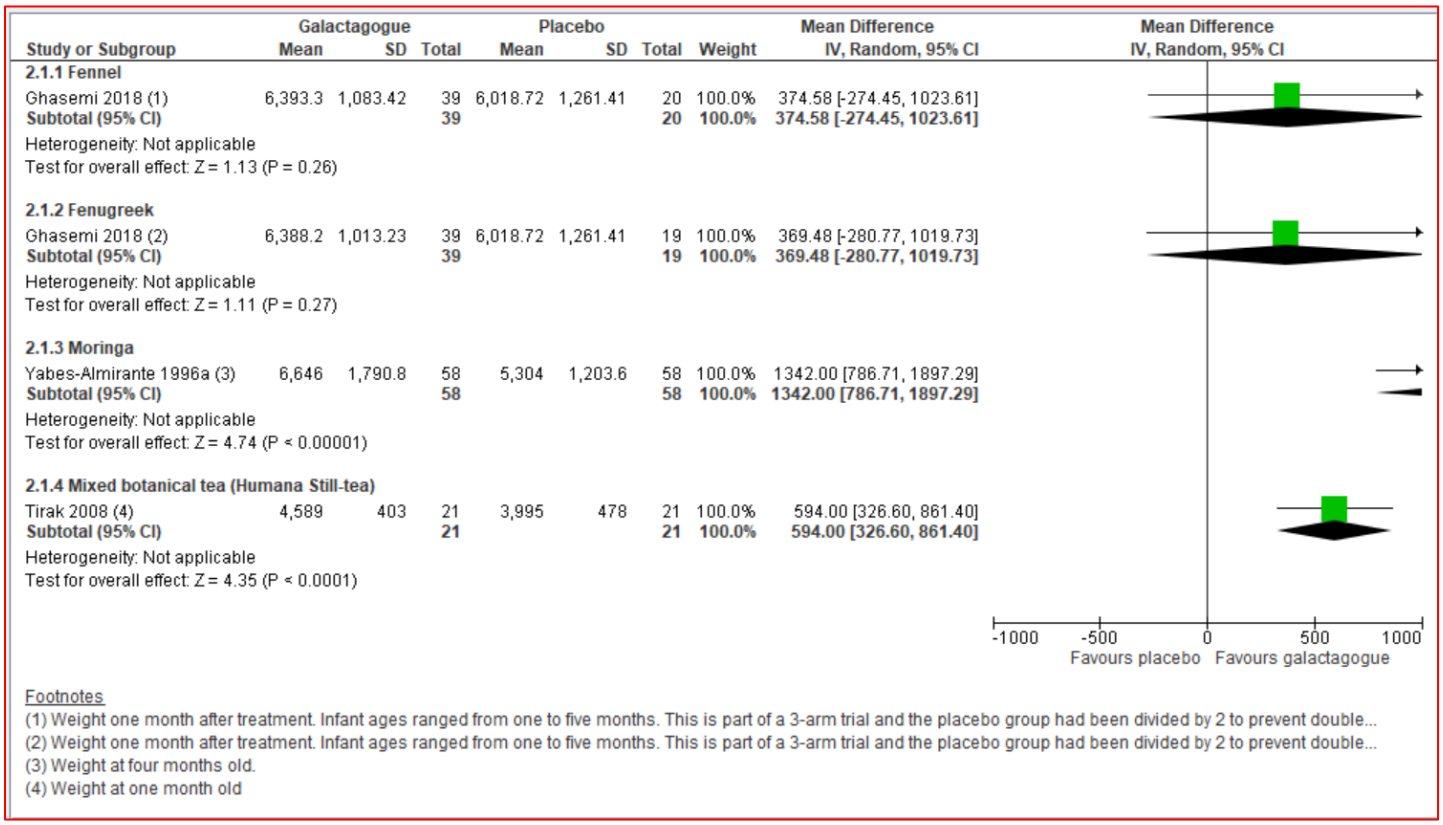
Outcomes	Anticipated absolute effects* (95% CI) Risk with placebo or no treatment	Risk with pharmacological oral galactagogues	Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
1: Proportion of infants bfg @ 3, 4, 6 mos	-	-	-	-	-	No studies reported this outcome
2: Infant weight (metoclopramide)	The mean infant weight was 0	MD 23 grams higher (47.71 lower to 93.71 higher)	-	20 (1 RCT)	⊕⊕⊖⊖ LOW [1]	
3: Milk Volume (all galactogogues)	The mean milk volume was 0	MD 63.82 mL higher (25.91 higher to 101.72 higher)	-	151 (3 RCTs)	⊕⊕⊖⊖ LOW [1]	
4: Adverse Effects (mother or infant)	With metoclopromide, tiredness, headache, nausea were reported more frequently than placebo group. With domperidone dry mouth were reported more frequently than placebo group and no extrapyramidal effects reported. With sulpiride tiredness and headache) were reported more frequently than placebo group. No adverse effects reported with thyrotropin-releasing hormone.		-	133 (5 RCTs)	⊕⊖⊖⊖ VERY LOW [2 3]	Adverse effects were generally poorly reported.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

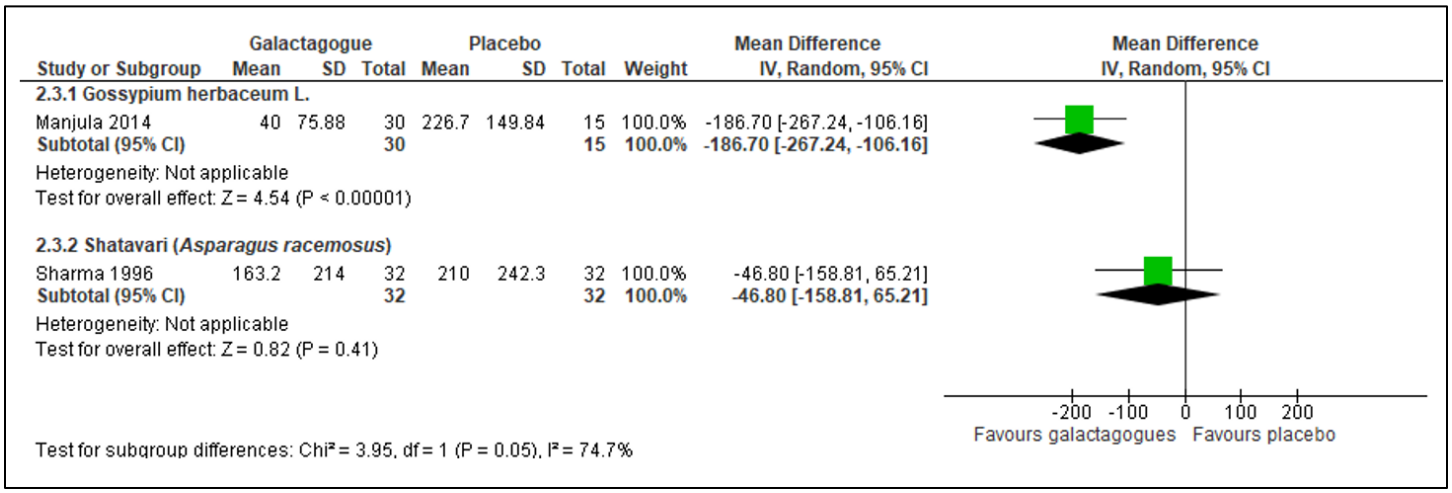
Comparison 2.1: Infant weight



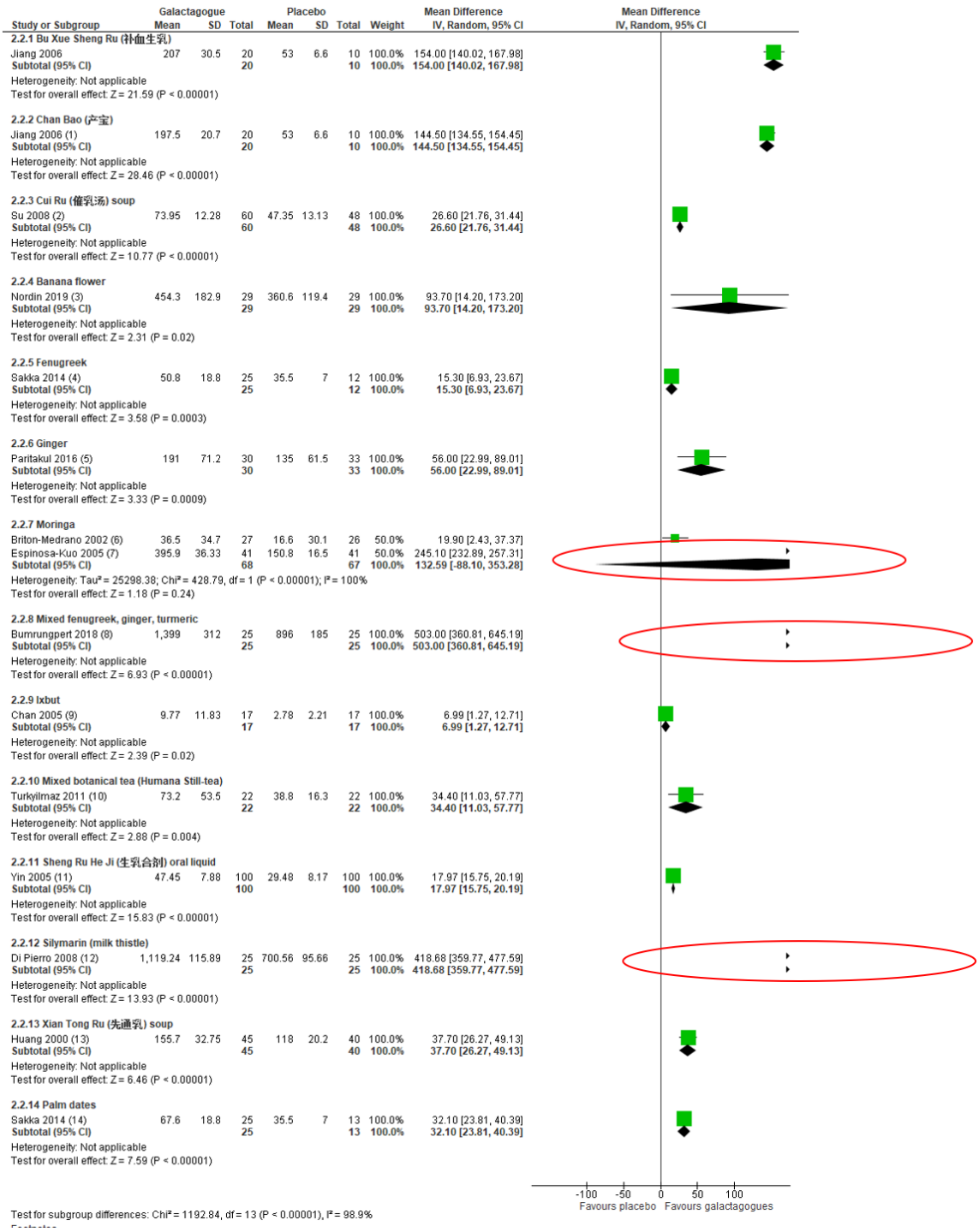
Footnotes

(1) Weight one month after treatment. Infant ages ranged from one to five months. This is part of a 3-arm trial and the placebo group had been divided by 2 to prevent double...
(2) Weight one month after treatment. Infant ages ranged from one to five months. This is part of a 3-arm trial and the placebo group had been divided by 2 to prevent double...
(3) Weight at four months old.
(4) Weight at one month old

Comparison 2.3: Volume of supplement



Comparison 2.2: Milk volume



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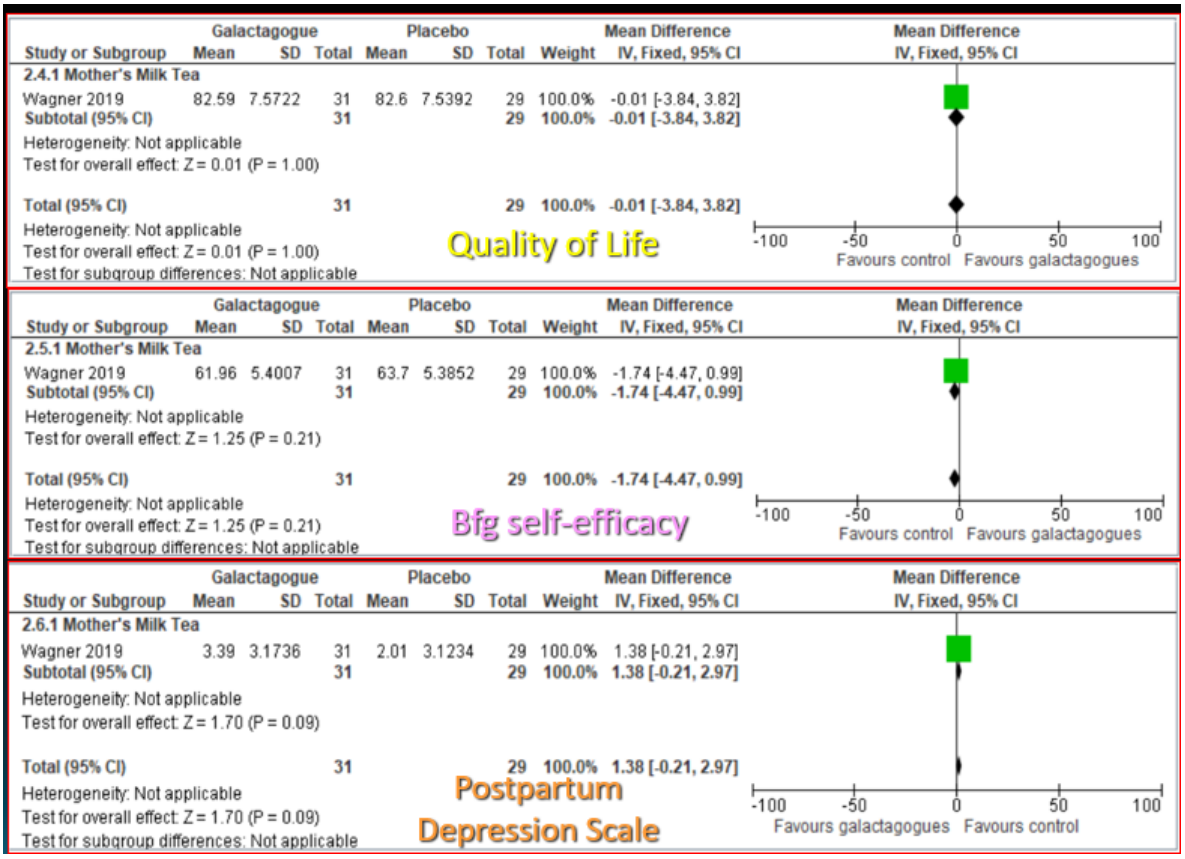
Comparison 2.4-2.6



Comparison 2 Summary

2 Natural oral galactagogues compared to placebo or no treatment for increasing breast milk production in mothers of non-hospitalised term infants

Natural oral galactagogues compared to placebo or no treatment for increasing breast milk production in mothers of non-hospitalised term infants

Patient or population: increasing breast milk production in mothers of non-hospitalised term infants
Setting: Community
Intervention: natural oral galactagogues
Comparison: placebo or no treatment

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with placebo or no treatment	Risk with natural oral galactagogues				
1: % of infants bfg @ 3, 4, 6 mos	One study reported no significant difference in breastfeeding rates at six months for Mother's Milk Tea.		-	72 (1 RCT)	⊕⊕⊖⊖ VERY LOW [1,2]	
2: Infant weight (metoclopramide)	see comment	see comment	-	275 (3 RCTs)	⊕⊖⊖⊖ VERY LOW [3,4]	Only subgroup analyses per galactagogue type. No meta-analysis .
3: Milk Volume (all galactogogues)	see comment	see comment	-	962 (13 RCTs)	⊕⊖⊖⊖ VERY LOW [3,4,5]	Only subgroup analyses per galactagogue type. No meta-analysis .
4: Adverse Effects (mother or infant)	Almost all reported "no adverse effects." Where reported, they were single occurrences such as maple-syrup urine with fenugreek, ginger and tumeric mix; nausea and urticaria in infants with Shirafza.		-	(10 RCTs)	⊕⊖⊖⊖ VERY LOW [2,7]	Adverse effects were poorly reported.

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
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Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

HETEROGENEITY OF STUDIES:

Study participants:

- ❖ Different ages of babies enrolled
- ❖ Breastfeeding routines frequently not described
- ❖ Normal supply vs low supply; causes of low supply
- ❖ Parity, c-section, etc.

Interventions and methodologies

- ❖ Dosages
- ❖ Treatment durations
- ❖ Natural botanical materials rarely validated
- ❖ Questionable placebos

Outcome measurements

- ✓ Using baby's gain- sometimes rate, sometimes weight
- ✓ Using milk transfer as a proxy for production- what about residual?
- ✓ Time points of measurement sometimes different for the groups

Insights: *Rescue Vs Proactive Study Goals*

CONCLUSION

- ✓ *Very low certainty evidence that oral galactagogues in the review might improve infant weight and milk volume*
- ✓ *We are uncertain if one galactagogue is better than another, or their use would result in any harm*
- *Due to substantial heterogeneity of the studies, imprecision of measurements and incomplete reporting, we are very uncertain about the magnitude of the effect*
- *Vert little available evidence of effect on bfg rates at 3, 4 or 6 mos*
- *Not enough evidence to judge harm*
- *Management should always be the first step before employing galactagogues=*

For quality evidence, we need:

- *High quality RC*
- *Set of core outcomes to standardize measurements*
- *Strong basis for dosages and forms used*

HOW TO BUILD A BETTER STUDY

- ✓ Methodology and reporting need to be at same academic standard as other pharmaceutical interventions
- ✓ Mandatory lactation support provided
- ✓ Infants of similar ages
- ✓ For botanicals, validation of material and purity
- ✓ Preparation of plant material described
- ✓ Rationale of form and dosage
- ✓ Measurement of milk by volume should include transfer & residual expressed, preferably 24 hrs
- ✓ Report total # of breastfeeding/expression sessions
- ✓ Report duration of 'any' and 'exclusive' bfg to 6 mos, *as that is the ultimate goal*
- ✓ Identify, screen for and report side and adverse effects in mother and baby

Priority for future Studies:

- ➢ For women with IMS, attempt to identify etiology of low production
- ➢ Test more commonly used galactagogues first
- ➢ Test multiple dosages to determine most effective therapeutic dosage

Priority – Related research needs

- ➢ Determine a standard for defining lactation insufficiency beyond maternal perception
- ➢ Determine a standard method to measure "milk volume", including measure tools and duration of measurement. Explore usefulness of Lai method
- ➢ Determine mechanisms by which a galactagogue may increase milk production. Take clues from animal studies. This may lead to better rationales for choosing one galactagogue over another

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